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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/533,427	03/22/2000	John A. Chiorini	14014.0323U2	8626

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	20

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/533,427	CHIORINI ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 11-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,16 and 17* is/are allowed.

6)☒ Claim(s) *2 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed April 9, 2003 (Paper No. 17) has been entered. Claims 1, 2, and 11 have been amended. Claims 3-10 have been cancelled. Claims 12-17 have been newly added.

Accordingly, Claims 1, 2, and 11-17 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

At page 9 of the response, with regard to the rejection of original Claims 1 and 2, Applicants argue that the filing date of U.S. Patent No. 6,391,858 (Podsakoff et al.) is January 4, 2001 and Applicants therefore conclude that the rejection is improper, as the filing date of the instant application is March 22, 2000. However, to clarify, the Examiner is relying on the effective filing date which is January 18, 1996. Thus, it is clear that the rejection of original Claims 1 and 2 under 35 U.S.C. 102(e) is proper. The rejection is withdrawn in view of the amendments to the claims.

Petition to Correct Inventorship

In view of the papers filed April 9, 2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Brian Safer as an inventor.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

The new Declaration executed by John Chiorini and Robert Kotin has been received and placed in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 12, and 13 are indefinite in their recitation of "wherein the nucleic acid is delivered intranasally" (or via aerosol or via the airway) because it is unclear if only the nucleic acid is delivered "intranasally" (or via aerosol or via the airway) or if the entire AAV5 particle is delivered by the route recited in the claim. Amending the claim to recite "wherein the AAV5 particle is delivered ..." would be remedial. This is a new grounds of rejection necessitated by Applicants' amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 stands rejected and Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,180,613 (Kaplitt et al., filed June 6, 1995) and Georg-Fries et al. (1984).

The claims are directed to delivering a nucleic acid to a cerebellar cell by administering an AAV5 particle containing a nucleic acid inserted between a pair of AAV inverted terminal repeats. Claim 15 specifically recites that the AAV5 particle is delivered directly to the brain of a subject.

Kaplitt et al. disclose a method for ameliorating a symptom of a central nervous system disorder in a mammal by administering an AAV vector to a target cell in the brain of the mammal. See Claim 1. Claim 11 specifically recites that the target cell is in the cerebellum. The specification and the claims read broadly on AAV vectors of any subtype, including AAV-5. Claim 1 specifically recites that the method comprises direct administration of an AAV vector to a target cell in the brain.

Georg-Fries et al. (1984) disclose that the type 5 adeno-associated virus has been known in the art since 1984.

Since AAV5 has been known in the art since 1984 and further since the claims of Kaplitt et al. read broadly on AAV vectors of any subtype, it is evident that in 1995 Kaplitt contemplated using AAV5 vectors, as well as AAV vectors of other subtypes, in practicing the claimed methods.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

At pages 11-12 of the response, Applicants argue that Georg-Fries et al. provides no AAV5 sequences and that it is the present application that discloses how to utilize the AAV5 genome and its subsequences as vectors to deliver nucleic acids to cerebellar cells. Applicants further argue that Kaplitt et al. provides no AAV5 sequences nor any guidance as to how to utilize the AAV5 genome and its subsequences for delivery of nucleic acids to a cerebellar cell. Applicants therefore argue that there is no reasonable expectation of success. Although Kaplitt et al. does not provide AAV5 sequences it would be routine for one of skill in the art to obtain these sequences and use them in the same manner as sequences from other AAV subtypes. Since the patent claims read broadly on any AAV vector it is evident that the Office considers the claims to be enabled for any AAV serotype. Further, since the claims of Kaplitt et al. are not limited to the specific AAV serotype exemplified in the working example, it is evident that the Office accepts that the claims are broadly enabled for any AAV serotype and that only routine experimentation is required to use other AAV serotypes. Since only standard molecular biology and cloning techniques are required to use the AAV5 serotype instead of another AAV serotype, one of skill in the art would have a reasonable expectation of success for using an AAV5 vector in the method disclosed by Kaplitt et al.

Conclusion

Claims 1, 16, and 17 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER